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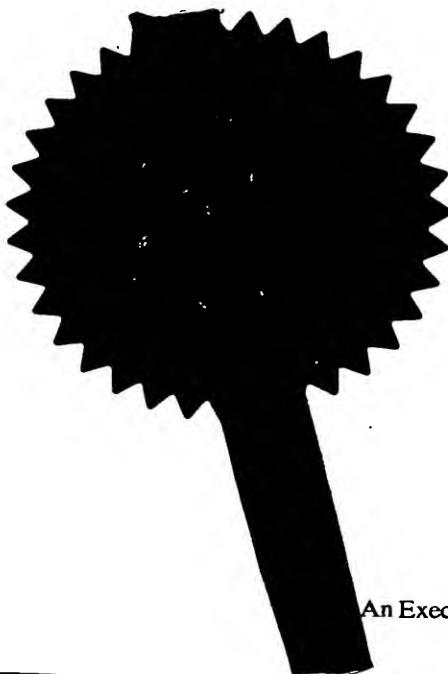
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1. Your Reference

CGP/PG4029

2. Patent application number

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**0011029.6**

3. Full name, address and postcode of the or of each applicant (underline all surnames)

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Patents ADP number (if you know it)

473587003

If the applicant is a corporate body, give the country/state of its corporation

4 Title of the invention

**REMOTE PATIENT ASSESSMENT SYSTEM**

5 Name of your agent (if you have one)

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Patents ADP number (if you know it)

7593981002

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Country

Priority application number  
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Date of Filing  
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7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing  
(day / month / year)

8. Is a statement of inventorship and of right to grant a patent required in support of this request? (Answer yes if:

- a) any applicant named in part 3 is not an inventor, or
- b) there is an inventor who is not named as an applicant, or
- c) any named applicant is a corporate body.

See note (d))

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Remote patient assessment system

- 5       The present invention relates to a system for the remote assessment of the medical condition of a patient. The system has an electronic data collection system and is capable of wireless communication with an entrypoint to a network computer system to enable communication of data between the network computer system and the electronic data collection system.
- 10      It is common prescribing practice for a doctor to prescribe a patient with medicament in a medicament dispenser together with instructions for patient administration of the medicament according to a defined treatment regime. The patient typically therefore, receives instructions relating to the correct use of the dispenser together with recommended dosing amounts, dose intervals and treatment period. The patient is then trusted to follow the treatment regime as set by the doctor.
- 15      A limitation associated with this practice is that the treatment regime is set at the time of prescription and can therefore not account for changes in the patient's condition over the treatment period. A further limitation associated with this practice is that the onus is on the patient to comply with the doctor's instructions. Occasionally, patients will forget to take the medicament or will vary the treatment regime in an unpredictable manner with possible consequences for the success of the treatment.
- 20      25     A variation on the above-described prescribing practice involves the use by a patient of a diagnostic device which enables data relating to their medical condition to be gathered on a regular basis. This data may for example, be collected prior to administration of any medicament and a correct dose amount calculated on the basis of the diagnostic data. An example of this practice would be that of a diabetic who checks their blood-sugar levels in order to calculate a required dose of insulin.
- 30      35     In developments of the practice variation, the diagnostic device may be integrated with the delivery system. Information relating to the patient's condition

integrated with a system for the provision of electronic prescriptions to enable seamless remote assessment and prescription of medicament.

- 5 According to one aspect of the present invention there is provided a system for the remote assessment of a patient's medical condition comprising a network computer system having specifiable network addresses; remote from said network computer system, a patient electronic data collection system for locally collecting data relevant to the patient's medical condition; a communicator for wirelessly communicating with an entrypoint to said network computer system to enable transfer of said data to a network address of the network computer system, wherein said network address is specific to the patient; and a secure access gateway enabling authorised users only to access the data at said patient-specific network address.
- 10
- 15 By remote it is meant that the patient electronic data collection system is physically, and potentially geographically distant from the entrypoint to the network computer system. In embodiments, it is envisaged that the patient data collection system is designed to be kept under the control of the patient e.g. it may be worn by the patient or be a handheld device always carried by the patient. Examples of patient-wearable devices would include belt attachable devices, devices in the form of watches for wrist or leg attachment and devices attachable as jewellery. Suitable body attachment means will be incorporated as required.
- 20
- 25 The communicator is local to the patient, for example being on the patient data collection system, or within another handheld device or present in the home or working environment of the patient. The communicator may for example, be in a device which mechanically coupled to a device housing the patient data collection system by any suitable mechanical mechanism including grip mechanisms and snap-fit mechanisms. In a preferred aspect, the data communicator forms a snap-in module and the device housing the patient data collection system is shaped for receipt of the module.
- 30
- 35 The network computer system by contrast, is typically located at, and under the control of, a healthcare provider or manager such as a doctor's practice, a

Preferably, the system additionally comprises a detector for detecting dispensing from the medicament container, wherein said detector communicates dispensing data to the electronic data management system.

5 Suitably, the data is communicable between the patient electronic data collection system and the patient-specific network address of the network computer system in encrypted form. All suitable methods of encryption or partial encryption are envisaged. Password protection may also be employed.

10 In one aspect, the data is continuously communicable between the patient electronic data collection system and the patient-specific network address of the network computer system.

15 In another aspect, the data is communicable in packet form between the patient electronic data collection system and the patient-specific network address of the network computer system.

Suitably, the secure access gateway is password protected.

20 Suitably, the secure access gateway enables different levels of access authorisation to the data to be assigned to different authorised users.

25 Suitably, the authorised users are selected from the group consisting of the patient, a healthcare professional such as a doctor or nurse, a pharmacist, an emergency assistance provider, a research professional, a database manager and any combinations thereof.

Suitably, information from a patient-remote datasource is made available to the patient-specific network address.

30 In one aspect, the patient-remote datasource comprises data relating to ambient environmental conditions such as weather conditions, or pollution, smog and pollen levels.

Suitably, the patient electronic data collection system further comprises a patient electronic data management system comprising a memory for storage of data; a microprocessor for performing operations on said data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data.

5                    Suitably, the patient electronic data management system additionally comprises a geographic positioning system such as a global positioning system or a system which relies on the use of multiple communications signals and a triangulation algorithm.

10                  Suitably, the communicator enables two-way transfer of data between the network computer system and the patient electronic data management system.

15                  Suitably, the system additionally comprises an authorised user data communicator comprising an authorised user electronic data management system comprising a memory for storage of data; a microprocessor for performing operations on said data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data; and a communicator for wirelessly communicating with an entrypoint to a network computer system to enable communication of data between the network computer system and the authorised user electronic data management system.

20                  25                  According to another aspect of the present invention there is provided a system for the remote assessment of a patient's medical condition and remote prescription therefor comprising a system as described above and additionally a first authorised user data communicator capable of communicating a prescription authorisation command to the patient-specific network address; and a second authorised user data communicator capable of receiving a prescription authorisation command from the patient-specific network address.

30                  Suitably, any communicator employs radiofrequency or optical signals.

35                  In one aspect, any communicator communicates directly with the gateway.

microprocessor. Preferably, the datalink comprises an infrared emitter and sensor.

5       Suitably, the patient electronic data management system additionally comprises a data input system for user input of data to the electronic data management system. More preferably, the data input system comprises a keypad.

10      Suitably, the patient electronic data management system additionally comprises a display for display of data from the electronic data management system to the user. The display may for example, comprise a screen such as an LED or LCD screen.

15      In one aspect, the system is suitable for the remote assessment of a patient's respiratory condition and additionally comprises a sensor which senses the breath of a user, wherein the sensor communicates breath data to the patient electronic data collection system.

20      Suitably, the sensor comprises a breath-movable element which is movable in response to the breath of a patient. Preferably, the breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

25      In another aspect, the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user.

30      In a further aspect, the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user.

35      In a further aspect, the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user. The temperature of the inhaled and exhaled part of the breath cycle varies and may, thus, be used as a measurement tool.

40      In a further aspect, the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user. The moisture content of the

member such as a spring, a source of compressed fluid such as a canister of compressed gas or a battery. Chemical energy sources are also suitable and might include chemical propellant or ignition mixtures. Other sources might include physical explosives such as liquefied or solidified gas in a canister which

5 burst when heated or exposed to the atmosphere.

The system may additionally comprise a safety mechanism to prevent unintended multiple actuations of the actuator. The patient is thereby protected from inadvertently receiving multiple doses of medicament in a situation where they take a number of short rapid breaths. More preferably, the safety mechanism imposes a time delay between successive actuations of the actuator. The time delay is typically of the order of from three to thirty seconds.

10 An actuation counter which can be mechanical or electronic may be provided to the system.

15 A medicament dispensing counter, such as a dose counter, may be provided to the system. This may be mechanical or electronic. The counter may be coupled to a visual display to provide feedback to the patient as to amount of drug released or remaining in the container.

20 A manual override can be provided to the system for use in the event of emergency or system failure.

25 In another aspect, the system is suitable for the remote assessment of a patient's cardiovascular condition and additionally comprises a sensor which senses the cardiovascular activity of a patient, wherein the sensor communicates cardiovascular data to the electronic data collection system. Preferably, the sensor measures the blood pressure of the patient.

30 According to another aspect of the present invention there is provided a method for remotely assessing a patient's medical condition comprising locally collecting data relevant to the patient's medical condition in electronic form; wirelessly communicating with an entrypoint to a remote network computer system to enable transfer of said data to a patient-specific network address of said remote

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communicated from the patient data collection system which may for example, reflect a change in the patient's condition. In one aspect, where the patient data collection system forms part of a medicament delivery system the 'update prescription' signal may be an alert that the levels of medicament in the delivery system are running low and that a re-prescription is needed.

5 Embodiments of systems according to the invention will now be described with reference to the accompanying drawings in which:

10 Figure 1. is a schematic representation of a first system in accord with the present invention in which the patient electronic data collection system forms part of a medicament delivery system;

15 Figure 2. is a schematic representation of a second system in accord with the present invention in which the patient electronic data collection system forms part of a medicament delivery system; and

20 Figures 3 and 4 are schematic representations of third and fourth systems in accord with the present invention in which the patient remote assessment system integrates with a system for electronic prescription of medicament.

Figure 1. shows a standard-form metered dose inhaler for the delivery of inhalable medicament comprising a tubular housing 10 in which an aerosol container 12 is located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. A dispensing outlet 14 leads laterally from the closed end of the housing 10. In the embodiment illustrated, the outlet 14 is in the form of a mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

30 The aerosol container 12 is located in the housing 10 so that one end protrudes from the open top of the housing 10. The aerosol container 12 has an outlet valve stem (not visible) at one end which connects with a support (not shown) in the housing 10. To dispense the dose, the protruding portion of the aerosol container 12 is depressed to move the container 12 relative to the valve stem to

The user accesses the electronic data management system 140 of the dispenser through the palmtop computer 170. The palmtop computer 170 itself, can communicate through a telecommunications link with computer network system 150. The computer network system 150 comprises a secure extranet computer system. As in Figure 1, remote information sources may also have access to the extranet. Two-way data transfer is possible between the electronic data management system and the computer network system 150 via the communications links with the palmtop computer 170. Information transfer is thus possible between the electronic data management system 140, palmtop computer 170 and any of the remote information sources.

Figure 3 shows a system herein in which patient electronic data collection system 240 communicates wirelessly with geographically distant network computer system 250. The network computer system 250 is itself wirelessly accessible by the system of a medicament prescriber 260 (e.g. a doctor's surgery system) and by the system of a pharmacist 262.

The system of Figure 3 may be employed in the remote assessment of a patient and electronic prescribing therefor as follows. The patient data collection system 240 communicates data relating to the medical condition of the patient to the network computer system 250. The medicament prescriber 260 wirelessly accesses this data e.g. by use of a palmtop communications and data management device and makes a judgement as to prescription needs. If a new prescription is needed the prescriber sends a 'prescription authorisation' signal to the network computer system 250. The pharmacist 262 then accesses the network computer system to receive the 'prescription authorisation' signal which authorises them to make up the prescription for the patient.

The system of Figure 4 is a variation of the system of Figure 3 in which patient electronic data collection system 340 communicates wirelessly with geographically distant network computer system 350. The network computer system 350 is itself wirelessly accessible by the system of a medicament prescriber 360 (e.g. a doctor's surgery system). The prescriber system 360 may also access second network computer system 354 which is accessible by the system of a pharmacist 362. In an alternative herein, the second computer

art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

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Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

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Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

15

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

20

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

25

6. A system according to claim 5, wherein the medicament delivery system provides respirable delivery of medicament to the patient.
- 5 7. A system according to claim 5, wherein the medicament delivery system provides injectable delivery of medicament to the patient.
8. A system according to claim 5, wherein the medicament delivery system is an implant in the body of the patient.
- 10 9. A system according to any of claims 1 to 8, wherein the data is communicable between the patient electronic data collection system and the patient-specific network address of the network computer system in encrypted form.
- 15 10. A system according to any of claims 1 to 9, wherein the data is continuously communicable between the patient electronic data collection system and the patient-specific network address of the network computer system.
- 20 11. A system according to any of claims 1 to 10, wherein the data is communicable in packet form between the patient electronic data collection system and the patient-specific network address of the network computer system.
- 25 12. A system according to any of claims 1 to 11, wherein the secure access gateway is password protected.
- 30 13. A system according to any of claims 1 to 12, wherein the secure access gateway enables different levels of access authorisation to the data to be assigned to different authorised users.
- 35 14. A system according to any of claims 1 to 13, wherein the authorised users are selected from the group consisting of the patient, a healthcare professional, a pharmacist, an emergency assistance provider, a research professional, a database manager and any combinations thereof.

- a microprocessor for performing operations on said data; and
- 5 a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data; and
- 10 a communicator for wirelessly communicating with an entrypoint to a network computer system to enable communication of data between the network computer system and the authorised user electronic data management system.
- 15 22. A system according to claim 21 for the remote assessment of a patient's medical condition and remote prescription therefor comprising
- a first authorised user data communicator capable of communicating a prescription authorisation command to the patient-specific network address; and
- 20 a second authorised user data communicator capable of receiving a prescription authorisation command from the patient-specific network address.
- 25 23. A system according to any of claims 1 to 22, wherein any communicator employs radiofrequency or optical signals.
24. A system according to any of claims 1 to 23, wherein any communicator communicates directly with the network computer system.
- 30 25. A system according to any of claims 1 to 24, wherein any communicator communicates with the network computer system via a second communications device.
- 35 26. A system according to claim 25, wherein the second communications device is a telecommunications device.
27. A system according to claim 26, wherein the telecommunications device comprises a cellular phone or pager.

38. A system according to claim 35, wherein the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user.

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39. A system according to claim 35, wherein the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user.

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40. A system according to claim 35, wherein the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user.

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41. A system according to claim 35, wherein the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user.

42. A system according to claim 35, wherein the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user.

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43. A system according to any of claims 35 to 42, wherein said breath data includes breath cycle data.

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44. A system according to any of claims 35 to 42, wherein said breath data includes peak flow data.

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45. A system according to any of claims 1 to 34 for the remote assessment of a patient's cardiovascular condition additionally comprising a sensor which senses the cardiovascular activity of a patient, wherein the sensor communicates cardiovascular data to the electronic data collection system.

46. A system according to claim 45, wherein said sensor measures the blood pressure of the patient.

a first authorised user communicating a prescription authorisation command to the patient-specific network address;

5 a second authorised user receiving said prescription authorisation command from the patient-specific network address; and

said second authorised user preparing the prescription based on the prescription authorisation.

10 55. A method according to any of claims 47 to 53 for remotely assessing a patient's condition and remotely prescribing therefor additionally comprising

a first authorised user communicating a prescription authorisation command to a pharmacy network address;

15 a second authorised user receiving said prescription authorisation command from the pharmacy network address; and

20 said second authorised user preparing the prescription for the patient based on the prescription authorisation.

25 56. A method according to either of claims 54 or 55, wherein the first authorised user communicates the prescription authorisation in response to a 'update prescription' alerting signal visible at the patient-specific network address.

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Fig. 1

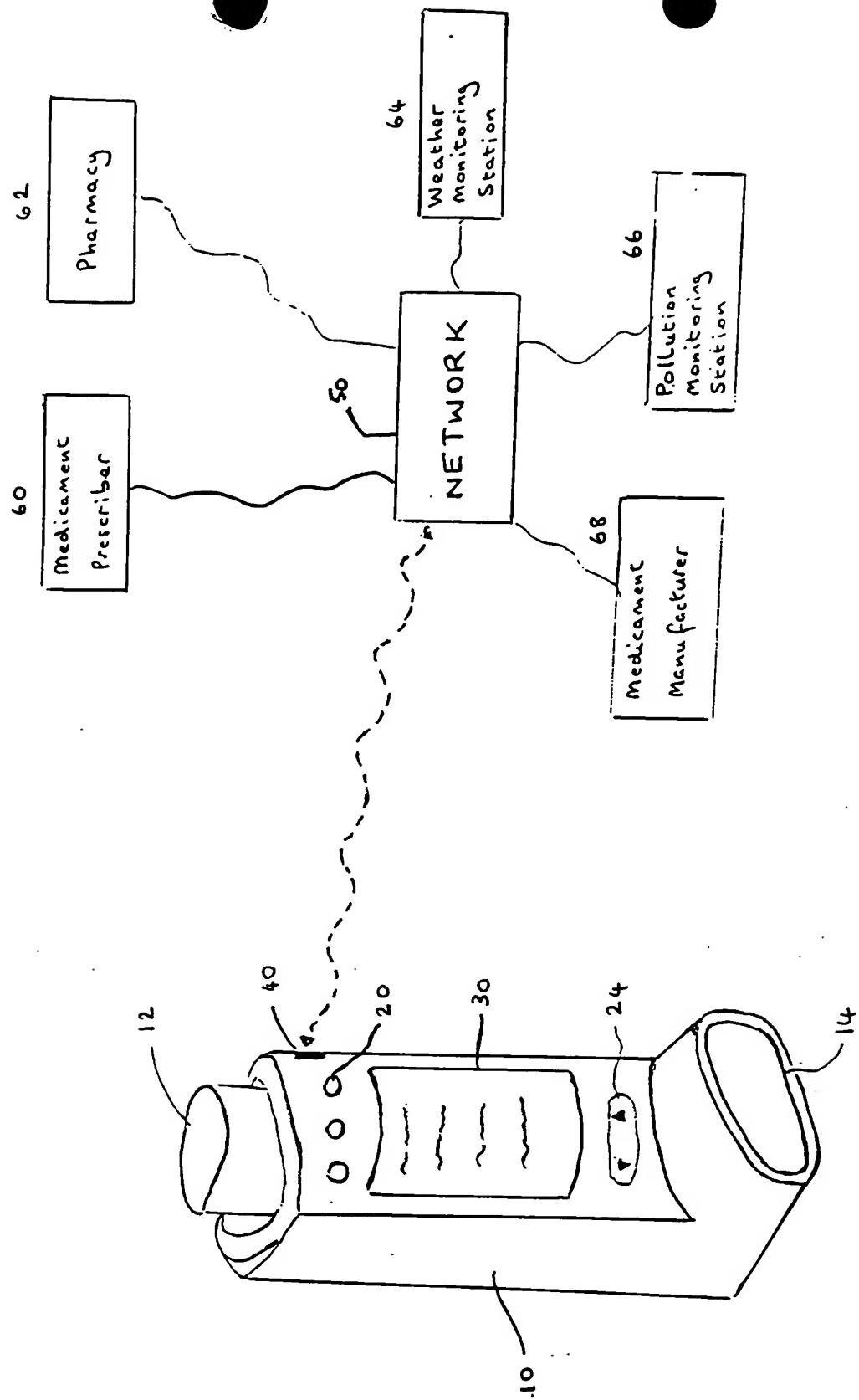
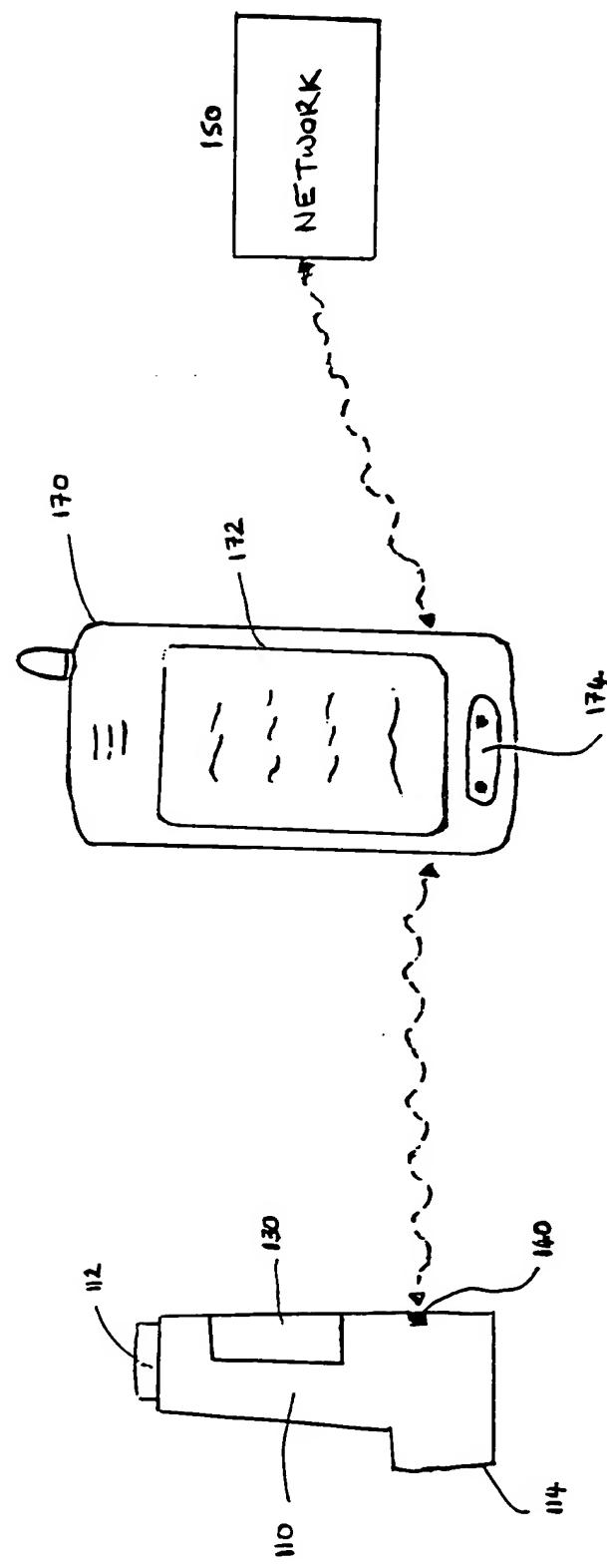


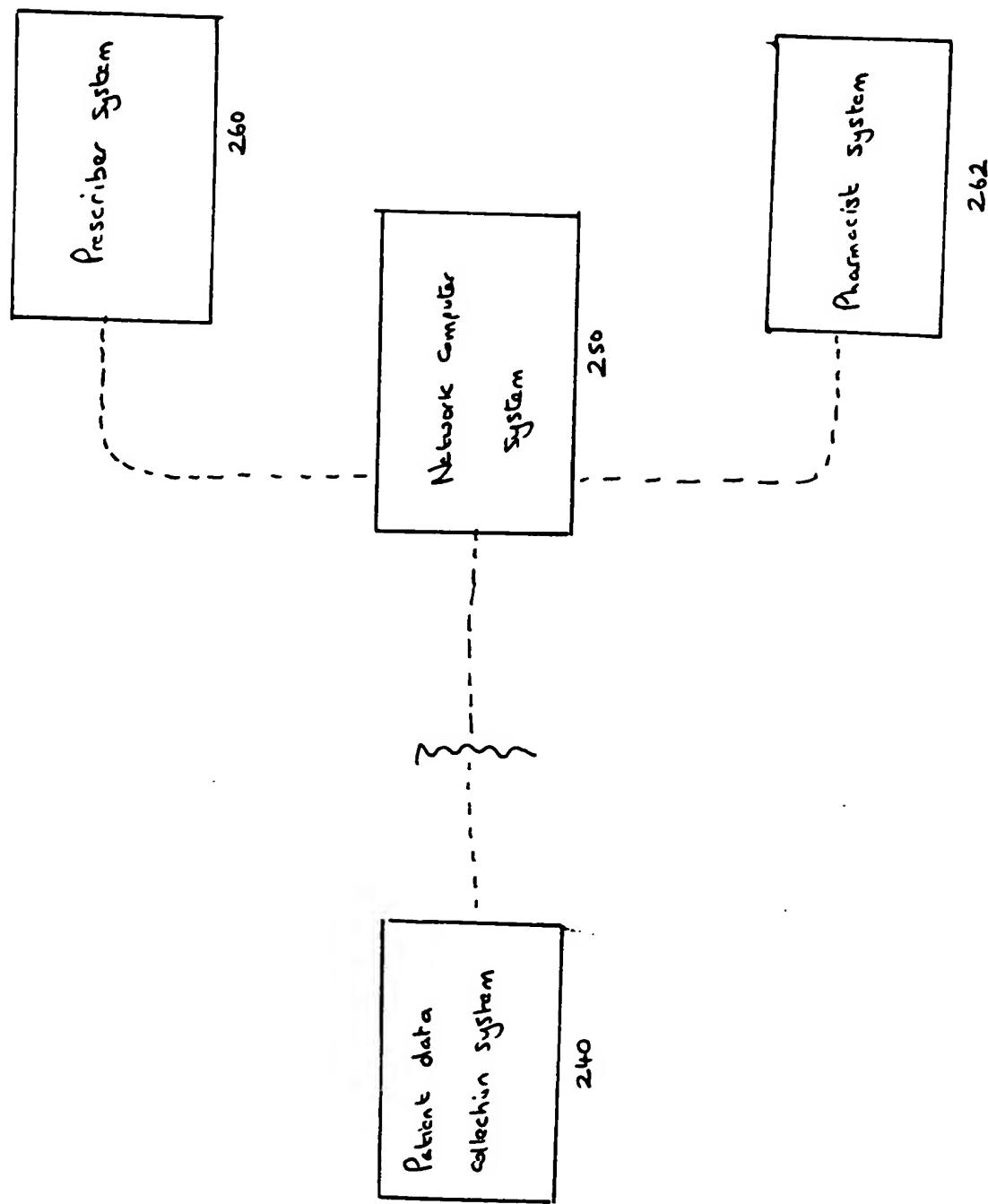
Fig 2.

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Fig. 3



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Fig 4.

